REMARKS

I. Status of the Claims

Claims 17-28 and 30-35 are pending in this application. Claims 26, 28, 32, and 33 have been amended. Claim 29 has been canceled. No new matter has been added by these amendments, as they are fully supported by the claims and specification as originally filed.

II. Rejections Under 35 U.S.C. § 112, First Paragraph

Claims 17-35 and separately claims 25-27 have been rejected under 35 U.S.C. § 112, first paragraph. The Examiner contends that the specification does not enable one skilled in the art to make and/or use the invention. (Office Action dated November 21, 2002, page 2, lines 10-13.) Applicants traverse these rejections, as their specification satisfies both prongs of the enablement requirement, *i.e.*, how to make and how to use the claimed subject matter.

The specification clearly teaches how to make and use the claimed subject matter. The enablement requirement is satisfied by disclosing in the specification at least one method for making and using the claimed subject matter, which bears a reasonable correlation to the entire scope of the claims. *See* M.P.E.P. § 2164.01(b). The teachings of the specification must be taken as being in compliance with the enablement requirement, unless there is a reason to doubt their objective truth. *See* M.P.E.P § 2164.04. Thus, Applicants' specification is compliant with the enablement requirement, unless and until the Examiner provides specific technical reasons as to *why* the specifications' teachings are doubted. *See* M.P.E.P § 2164.04.

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Here, the specification discloses general methods of making the claimed subject matter and contains thirty-six specific preparatory examples. (Specification, pages 3-8 and 13-65.) The Examiner has provided absolutely no reason (whether specific, technical, or otherwise) why one of skill in the art would not be able to make the claimed subject matter in accordance with these disclosures. Thus, without any reasoning or evidence to refute them, these teachings must be taken as satisfying the "how to make" prong of the enablement requirement.

With respect to the "how to use" prong of the enablement requirement, the Examiner contends that the specifications' asserted utility is not incredible, but that enablement is lacking. (Office Action dated November 21, 2002, page 5, lines 5-6.) The disclosures set forth in Applicants' specification are objective truths, which are presumed true unless there is a reason to doubt them. Beyond the Examiner's conclusory statement, however, sufficient doubt as to the truthfulness of the statements made in the specification has yet to be raised.

The specification teaches that the claimed streptogramin derivatives can be used as antibacterials (page 8, lines 12-15). The specification teaches several routes and forms of administration, *e.g.*, oral, parenteral, topical, and rectal routes of administration and also, for example, administration in aerosol form (page 65, lines 21-23). The specification teaches how to administer by specifying dosages (page 67, lines 18-28). The specification additionally teaches a working example for tablets comprising such dosages (page 68, lines 3-12). The specification teaches that several references have established that streptogramins are a recognized class of antibacterials (page 2, line 7—page 3, line 5). The specification teaches metabolic stability results (page 8, lines 15-19), *in vivo* dosing and results (page 11, lines 20-25), and low toxicity results (page

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11, lines 26—page 12, line 2). As noted above, all of these statements in the specification by the Applicants must be taken as true, unless the Examiner contradicts the statements with evidence. For additional support, Applicants refer the Examiner to the article submitted with the concurrently-filed Information Disclosure Statement.

In particular, to put Applicants' asserted utility in question, the Examiner is obligated to enter into the record evidence that is "inconsistent" with the statements of the specification, nothing less. *See* M.P.E.P § 2164.04. Instead, over the course of prosecution, the Examiner has relied upon eighteen references, not one of which specifically concerns the claimed subject matter and not one of which sufficiently refutes the statements of the specification. For example, the Examiner has cited four references, respectively concerning (1) pyridazine N-oxides, (2) haliangicin, (3) cecropin-melittin hybrid peptides, and (4) amphipathic antimicrobial peptides, that purportedly provide that some compounds exhibit no antibacterial activity, while their structurally-similar counterparts do. In previous Office Actions, the Examiner has cited three references that show the failure of some compounds in treating ulcers, two references dealing with the subject of antibiotic resistance, and one reference showing that some compounds may work *in vitro*, while not working *in vivo*. Not one of the references concerns streptogramins.

The Examiner has also cited seven references directed to the general issue of statistical analysis pertinent to inadequate experimental design. The Examiner admits that "[n]one of these references 'proves' that the assertion on page 11 line 20+ of the specification is invalid" but that they instead "raise sufficient doubt at to impose upon applicants the burden of at least providing experimental details, and an explanation of how the various data were analyzed." (Office Action dated November 21, 2002, pages

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7-8.) Applicants disagree. To raise sufficient doubt about the statements in Applicants' specification, the Examiner must present technical reasons, specific to the claimed subject matter and inconsistent with the statements of the specification. The references presented by the Examiner individually and in total fail to provide specific technical support for doubting the exhaustive teachings of the specification at issue. Thus, the claims remain presumptively enabled by the specification because the Examiner has failed to impeach the truth of the statements therein.

Applicants further note that the Examiner's request for *in vitro* data is premature. (Office Action dated November 21, 2002, page 8, lines 3-5.) Unless and until the Examiner has established a *prima facie* case of nonenablement by impeaching the statements of the specification, Applicants are not required to substantiate their presumptively correct disclosure. *See In re Brana*, 51 F.3d 1560, 1566 (Fed. Cir. 1995) (The court noted that because the Patent Office failed to satisfy its burden of showing that one would reasonably doubt applicants' asserted utility, "[A]pplicants should not have been required to substantiate their presumptively correct disclosure to avoid a rejection under 35 U.S.C. § 112, first paragraph.")[1] In view of the above, Applicants request withdrawal of the 35 U.S.C. § 112, first paragraph, rejections.

III. Rejections Under 35 U.S.C. § 112, Second Paragraph

The Examiner has rejected claims 25-30 under 35 U.S.C. § 112, second paragraph, raising multiple independent issues that have been addressed by Applicants

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[1] The Examiner summarily dismisses *In re Brana* because it allegedly concerns "utility" and not enablement. (Office Action dated November 21, 2002, page 5, lines 6-11.) Contrary to what the Examiner contends, however, Applicants respectfully point out that *In re Brana* is properly relied upon in this case, as the "how to use" prong of the enablement requirement to some extent concerns utility, as is discussed in the cited case. Further, Applicants note that in *In re Brana*, the Court of Appeals for the Federal Circuit reversed the Board's affirmance of the Examiner's rejection under 35 U.S.C. § 112, first paragraph. *In re Brana*, 51 F.3d 1560, 1562 (Fed. Cir. 1995).

in previous responses. Applicants maintain that if the scope of the invention can be determined from the language of the claims with a reasonable degree of certainty, then any rejection under 35 U.S.C. § 112, second paragraph, is improper. Applicants' claims meet this statutory standard and, thus, the rejections should be withdrawn.

For example, Applicants are not required to amend claim 25 to substitute the examiner's preferred term "isolate" for the term "separate." Nor are Applicants required to amend claims 26 or 27 to add an isolation step. Because such isolation means are known to the basic chemist and because conventional methods of isolation and separation are disclosed, for example, on page 7 of the specification, one of ordinary skill in the art would be reasonably apprised of the scope of claims 25-27.

Applicants have amended claim 26 by changing the phrase "capable of forming" formaldehyde to the phrase "to generate" formaldehyde. Applicants previously complied with a similar request made by the Examiner over claim 25, thus, this amendment should eliminate the Examiner's objection to claim 26.

Further, Applicants disagree with the Examiner's analysis of claim 27 in that the term "desired" does not suggest an emotional component. Claim 27 specifically refers to the R″ groups of claim 17. Thus, one of skill in the art would know which R″ group to select to perform a reaction in accordance with claim 27.

Applicants respectfully submit that all of claims 25-30 meet the statutory threshold of 35 U.S.C. § 112, second paragraph. Accordingly, Applicants respectfully request withdrawal of these rejections.

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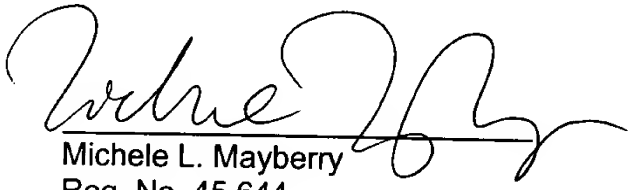
IV. Conclusi n

In view of the foregoing remarks, Applicants respectfully request the reconsideration and reexamination of this application and the timely allowance of the pending claims.

Please grant any extensions of time required to enter this response and charge any additional required fees to our Deposit Account No. 06-0916.

Respectfully submitted,

FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER, L.L.P.



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Date: March 21, 2003

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